

In The United States Patent Office

5 :
:
:
:
:
10 *In re Application of Juan Luis HANCKE* : Art Unit 1625
et al., *Diterpenic Lambdanes...* : Serial No. 10/516,500
: Filed 3 February 2004
:
:
:
15 :
:
:
:
-----:

RULE 41.43(b)
SUPPLEMENTAL
REPLY BRIEF

TABLE OF CONTENTS

TABLE OF CONTENTS	II
INTRODUCTION.....	1
5 THE EXAMINER ATTEMPTS TO DECEIVE THE BOARD BY FRAUDULENTLY ALTERING THE EVIDENCE	1
THE EXAMINER MISLEADINGLY ALTERS BABISH '350.....	1
THE EXAMINER MISLEADINGLY ALTERS BABISH '605.....	3
ALLEGED "TYPOGRAPHICAL ERRORS" DOES NOT PROVIDE THE EXAMINER LICENSE TO ALTER EVIDENCE.....	4
10 STN REGISTRY	5
THE SUPPLEMENTAL OFFICE ACTION MAKES A NUMBER OF NEW FACTUAL ALLEGATIONS, YET FAILS TO SUPPORT ANY OF THESE WITH EVIDENCE	6
THE EXAMINER FAILS TO SUPPORT HER NEWLY-RAISED ALLEGATIONS REGARDING SYNDROME X	6
THE EXAMINER FAILS TO SUPPORT HER NEWLY-RAISED ALLEGATIONS REGARDING THE CLAIMED DOSAGE AMOUNT	7
THE EXAMINER FAILS TO SUPPORT HER NEWLY-RAISED ALLEGATION THAT THE IUPAC NAME FOR "ANDROGRAPHOLIDE" IS THE CLAIMED COMPOUND	8
REPEATING THE NAME ANDORGRAPHOLIDE "OVER AND OVER" DOES NOT CHANGE THE PRIOR ART COMPOUNDS INTO THE CLAIMED COMPOUND	9
20 PRAYER FOR RELIEF.....	10

TABLE OF AUTHORITIES

5	<u>CASES</u>	
	<i>Ex parte Levy</i> , 17 USPQ2d 1461, 1464 (BPAI 1990)	8
	<i>In re Ahlert</i> , 424 F.2d 1088, 1091 (CCPA 1970)	6
	<i>In re Eynde</i> , 480 F.2d 1364, 1370 (CCPA 1973)	6, 8
	<i>In re Grose</i> , 592 F.2d 1161, 1167-68 (CCPA 1979)	6
10	<i>In re Robertson</i> , 169 F.3d 743, 745 (Fed. Cir. 1999)	7
	<i>In re Zurko</i> , 258 F.3d 1379, 1385 (Fed. Cir. 2001)	6

INTRODUCTION

This SUPPLEMENTAL REPLY BRIEF is submitted in response to the Board's DECISION ON PETITIONS (16 Nov. 2009). This SUPPLEMENTAL REPLY BRIEF is filed within two months of the DECISION ON PETITIONS; this paper is thus respectfully believed timely filed.

5 This application has been granted Special status. Expedited resolution of this appeal is therefore respectfully requested.

10 THE EXAMINER ATTEMPTS TO DECEIVE THE BOARD BY FRAUDULENTLY ALTERING THE EVIDENCE

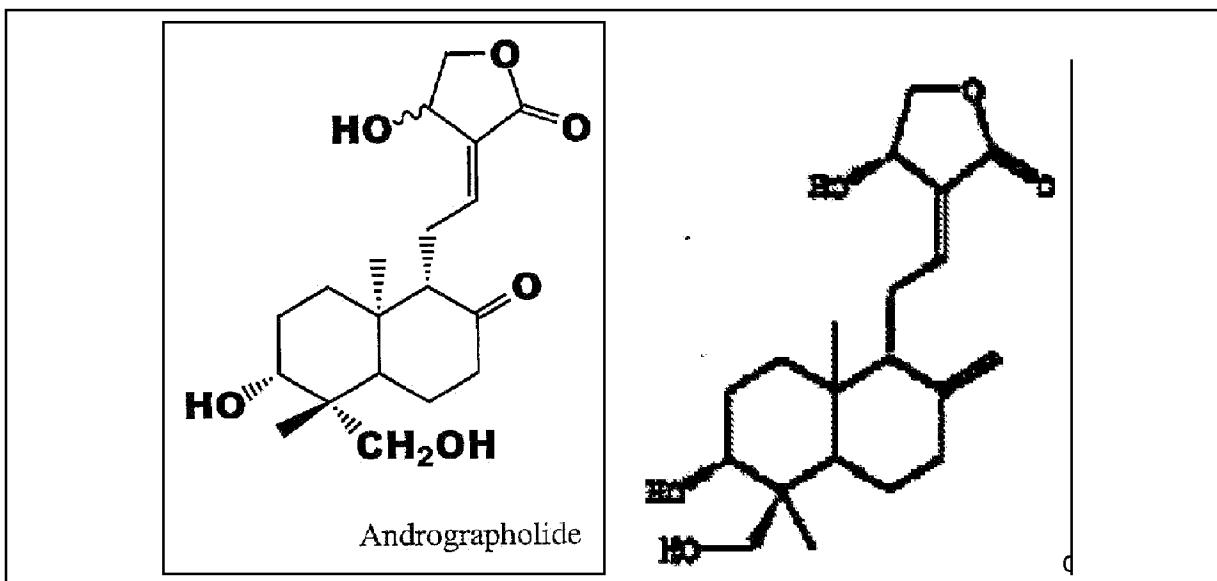
The Examiner apparently recognizes that her various references do not in fact support her position. The Examiner now responds by providing the Board with misleadingly altered evidence.¹

15 The Examiner misleadingly alters BABISH '350

The Examiner now apparently recognizes that John G. BABISH *et al.*, U.S. Patent Publication No. 2002/0077350 (2002) ("BABISH '350") at Figure sheet 2,

¹ This is not the first time the Examiner has tried this. In her 1 August 2006 office action (at ¶ 6), the Examiner altered a Chemical Abstracts registry record No. RN 5508-58-7. When Appellant caught her at it, *see* J.L. HANCKE, SUPPLEMENTAL RULE 132 DECLARATION (filed 18 October 2006) at ¶¶ 1, the Examiner withdrew the rejection, *cf.* 19 January 2007 Office Action.

compound [C3], “Andrographolide” teaches a structure different from the claimed compound. Rather than conceding error, however, she now provides the Board with an *altered version* of BABISH. Her attempt to deceive the Board can be seen by comparing the structure for Andrographolide shown in BABISH ‘350 (reproduced below at left with its legend, “Andrographolide”) to the altered structure (reproduced below on the right) which the Examiner presents to the Board in her *Supplemental Examiner’s Answer* at page 10 as a “reproduction” of the original:



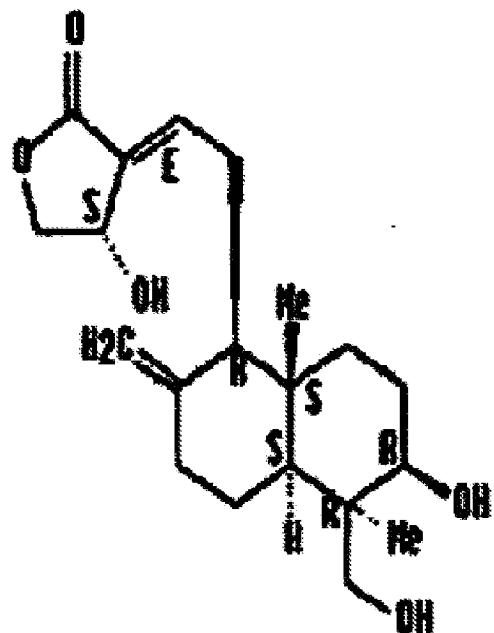
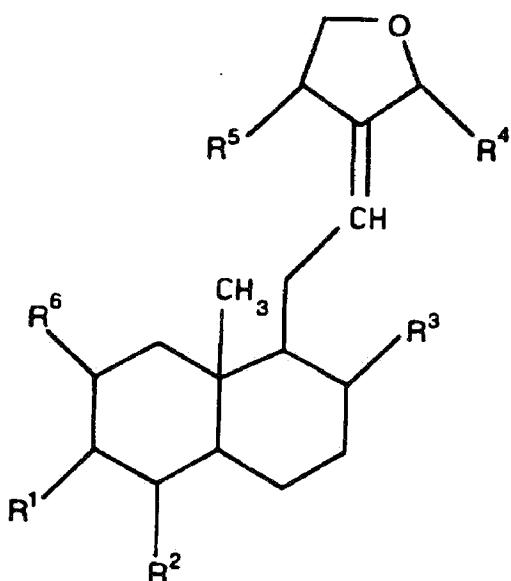
Comparing the structure actually taught by BABISH '350 to the altered structure the Examiner provides to the Board, shows that the Examiner improperly altered BABISH's structure by, for example, concealing the fact that BABISH '350 teaches an oxygen at residue #15, concealing the fact that BABISH teaches methanol at #25, concealing the fact that BABISH teaches hydrogen at #11, etc.

5

The Examiner misleadingly alters BABISH '605

Similarly, the *Supplemental Examiner's Answer*, at page 15, claims to "reproduce" Figure 6 of John G. BABISH *et al.*, WO96/17605 (1996) ("BABISH '605"). The Examiner, however, provides the Board with a Figure which has been 10 misleadingly altered. The extent of the Examiner's alterations are readily seen by comparing BABISH '605 Figure 6 (below, on the left, with its "Figure 6" legend) to the altered version which the Examiner provides in her *Supplemental Examiner's Answer* at page 15 (below, on the right):

Figure 6



Alleged “typographical errors” does not provide the
Examiner license to alter evidence

The *Supplemental Examiner’s Answer* (at e.g., 11, 14) concedes that “different structures are disclosed” by the art of record. The *Supplemental Examiner’s Answer*, however, argues that the structures taught by the prior art contain typographical errors. *See Supplemental Examiner’s Answer* at e.g., page 17, page 18 (“the compound [C3], which has the (=O) and is typo.”). This argument is not, however, relevant: the prior art teaches what the prior art teaches, regardless of

whether the prior art is correct or not. Alleged “typos” do not give the Examiner license to falsify the evidence.

STN REGISTRY

The *Supplemental Examiner’s Answer* (at e.g., 22) attempts to contradict the 5 explicit teachings of the art of record by relying on a reference called “the STN REGISTRY.” The *Supplemental Examiner’s Answer* argues that STN REGISTRY need not be made of record because it “was used in final office action dated on 01/19/2007.”

The Examiner’s allegation is factually correct; her final office action dated 10 01/19/2007 does rely on STN REGISTRY. The final office action, however, refused to make a copy of STN REGISTRY of record, nor provide a copy to the Appellant. *See Notice of References Cited* (19 Jan 2007). Since then, the Examiner has steadfastly refused to provide a copy of it to the Appellant, nor even to the Board.

Given the Examiner’s propensity for altering the art which *is* of record, *see* 15 *supra*, the Board should not blindly accept the Examiner’s allegations regarding the substance a reference which she has for three years steadfastly withheld from the Board.

THE SUPPLEMENTAL OFFICE ACTION MAKES A NUMBER OF NEW
FACTUAL ALLEGATIONS, YET FAILS TO SUPPORT ANY OF THESE
WITH EVIDENCE

5 The Examiner Fails To Support Her Newly-Raised
Allegations Regarding Syndrome X

The *Supplemental Examiner's Answer* speculates (at e.g., 19, 23, 26) that it is
“well known by the ordinary artisan” that syndrome X includes irritable Bowel
syndrome, HIV, AIDS, viral infection, cancer, autoimmune disease and Alzheimer’s
Disease. The Examiner, however, fails to provide the Board with any support for her
10 speculation.

What is allegedly well known by the skilled artisan is “normally subject to the
possibility of rational disagreement among reasonable men,” and thus must be
supported by evidence. *See In re Eynde*, 480 F.2d 1364, 1370 (CCPA 1973); *In re
Ahler*, 424 F.2d 1088, 1091 (CCPA 1970); *In re Grose*, 592 F.2d 1161, 1167-68
15 (CCPA 1979); *In re Zurko*, 258 F.3d 1379, 1385 (Fed. Cir. 2001) (“the Board cannot
simply reach conclusions based on its own understanding or experience-or on its
assessment of what would be basic knowledge or common sense. Rather, the Board
must point to some concrete evidence in the record in support of these findings.”).

In the instant case, the Examiner does not bother to provide the Board with any
20 evidence supporting her speculations regarding Syndrome X. Thus, the Board must
disregard the Examiner’s speculations.

The Examiner Fails To Support Her Newly-Raised
Allegations Regarding The Claimed Dosage Amount

The Examiner does not dispute that the prior art fails to teach the claimed amount of compound. In response, the *Supplemental Examiner's Answer* now speculates (at e.g., 19) that the claimed amount “is inherently there.”²

To establish inherency, however, the Examiner must provide extrinsic evidence which proves that the claimed limitation is necessarily present in the thing described in the reference, and that it would have been so recognized by persons of ordinary skill. *See In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (Inherency “may not be established by probabilities or possibilities. The mere fact that a certain thing may result . . . is not sufficient.”); *Ex parte Levy*, 17 USPQ2d 1461, 1464 (BPAI 1990).

In the instant case, the Examiner provides the Board with no evidence showing the claimed amounts are “necessarily” present in BABISH ‘098. The

² In several previous *Answers*, the Examiner raised new grounds of rejection, but refused to properly identify them as such. To prevent the Examiner from continually shifting position on appeal, on March 31 the Board *Ordered* the Examiner to properly identify any new grounds for rejection, and to obtain Director approval for any new grounds. *See Order* (31 March 2009). Here, the Examiner raises a new grounds of rejection (she does not appear to have even mentioned the word “inherent” in the previous five years of prosecution), but she nonetheless flatly refuses to comply with the Board’s March 31, 2009 *Order*, refusing to designate this new grounds of rejection as such and refusing to obtain Director approval therefore.

Examiner's speculation thus fails to provide the Board with a *prima facie* case of inherent anticipation.

5 **The Examiner Fails To Support Her Newly-Raised Allegation That The IUPAC Name For "Andrographolide" Is The Claimed Compound**

The IUPAC name for the claimed compound is 3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone. *See* J.L. HANCKE, RULE 132 DECLARATION (9 September 2006) at ¶¶ 7-8; J.L. HANCKE, SUPPLEMENTAL RULE 132 DECLARATION (20 September 2006) at ¶¶ 1-3. This IUPAC name denotes a compound with a structure different from the various prior-art compounds. *Id.*

10 The *Supplemental Examiner's Answer* (at *e.g.*, 10 and 13) flatly ignores the inventor's testimony, and speculates that this IUPPAC name denotes a compound called "Andrographolide." The Board must disregard the Examiner's speculation, however, because she provides the Board with no evidence to support it. *See e.g. In re Eynde*, 480 F.2d 1364 (CCPA 1973).

Repeating The Name Andrographolide “Over And Over”
Does Not Change The Prior Art Compounds Into The
Claimed Compound

In fairy tales, repeating a magic phrase can turn dross into gold, or return

5 Dorothy to Kansas; in organic chemistry, repeating a name - no matter how often - does not magically change the structures actually taught by the prior art into the claimed compound.

In the instant case, however, the *Supplemental Examiner’s Answer* (at e.g., 5-6) argues that the Board should ignore the explicit teachings of the art of record and 10 instead rely on the alleged contrary teachings of a reference not of record (the STN Registry) because the references of record “repeat[] the name ‘Andrographolide’ over and over.”

The Examiner confuses organic chemistry with magic. The evidence of record corroborates the inventor’s testimony that the term “andrographolide” is used to 15 denote a variety of compounds, each one different from the claimed compound. *See* e.g., J.L. HANCKE, RULE 132 DECLARATION (9 September 2006) at ¶ 6; *compare* BABISH (2002) at Figure 2 [B2], Srinivas NANDURI *et al.*, U.S. Patent No. 6,410,590 (2002) at 2:26-42 and at 1:15-30. Repeating the phrase “andrographolide” “over and over” – no matter how often – does not turn the various 20 prior art compounds into the claimed one.

PRAYER FOR RELIEF

Applicant respectfully requests the Board reverse all pending rejections and order the Examiner to issue a NOTICE OF ALLOWANCE.

Respectfully submitted on behalf of the Applicant by its attorneys,
5 PHARMACEUTICAL PATENT ATTORNEYS, LLC

/s/
Mark Pohl, Reg. No. 35,325

10 Pharmaceutical Patent Attorneys LLC
55 Madison Avenue, 4th floor
Morristown, NJ 07960-6397 USA
7 December 2009

15 SD:/HP Ingredients/1-.516,500 Reply Brief (November 2009)